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APPLICATION NO. 087897,455	FILING DATE 07/22/97	STACHE FIRST NAMED INVENTOR	U	2481,1403-02	ATTORNEY DOCKET NO.
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FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

DABIO, B
EXAMINER

1209 ART UNIT	PAPER NUMBER
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11/19/97
14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/897,455

Applicant(s)
Stache et al.

Examiner
Barbara Badio

Group Art Unit
1209



☒ Responsive to communication(s) filed on Jul 22, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) 3 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 4, and 5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1209

First Office Action on the Merits of a File Wrapper Continuation

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2 and 4-5, drawn to compounds, compositions and method of use, classified in class 540, subclass 108 and others.
 - II. Claim 3, drawn to a method of making compounds, classified in class 552, subclass 569 and others.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as formation of the 17-ester from the corresponding alcohol.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1209

4. Claims 1-5 are generic to a plurality of disclosed patentably distinct species comprising the species of examples 1-61 and Tables 1-2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Since this is a continuation of application Serial No. 08/590,624, filed January 24, 1996, now abandoned, which is a continuation of application Serial No. 08/310,791, filed September 29, 1994, now abandoned, and applicant has not indicated otherwise, the examiner assumes that the election of Group I, claims 1-2 and 4-5 and the species of Example 6, made in application Serial No. 08/590,624 carries forward to this application.

Accordingly, claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Generic claims 1-2 and 4-5 will be examined to the extent that they read on the elected species.

Art Unit: 1209

Duplicate Claims

6. Claims 1 and 2 are objected to under 35 U.S.C. 101 as being a substantial duplicate thereof. When one claim is allowed, the other claim will be rejected as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 2 states that R² is linear or branched (C₁-C₈)-alkyl, phenyl or benzyl and the other variables are as defined in claim 1. However, these are the only possibilities for R² in claim 1 and, thus, the claims defined the same genus of compounds.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Villax et al. ('693).

Villax et al. teach 17,21-dicarboxylic ester having an aromatic group in the acid moiety attached at the 21-position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-

Art Unit: 1209

dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-benzoate (col. 4, lines 23-42). It also teaches that these compounds may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses (col. 4, lines 48-62). These compounds, compositions and method of use of the compounds are encompassed by the instant claims.

9. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamano et al. ('172).

Kamano et al. teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione (col. 9, Table 1, compounds 8 and 12). The reference teaches that the compounds can be formulated into compositions useful for the treatment of dermal disorders (col. 8, lines 17-23 and 42-47). These compounds, compositions and method of use of the compounds are encompassed by the instant claims.

11

Art Unit: 1209

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villax et al. ('693).

Villax et al. teach 17,21-dicarboxylic ester having an aromatic group in the acid moiety attached at the 21-position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-benzoate (col. 4, lines 23-42). It also teaches that these compounds may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses (col. 4, lines 48-62).

The instant claims differ from the reference by reciting additional compounds having halogens, methyl, etc. groups in the 6, 9, 11 and 16 positions. However, it is

Art Unit: 1209

well known that compounds having similar structures have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-3,20-diones having an optional double bond in the 1 and/or 9 positions or being substituted with similar groups in the 9, 11 and 16 positions. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the compounds of the reference, including those of the instant claims, with reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

12. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamano et al. ('172).

Kamano et al. teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione (col. 9, Table 1, compounds 8 and 12). The reference teaches that the compounds can be formulated into compositions useful for the treatment of dermal disorders (col. 8, lines 17-23 and 42-47). These compounds, compositions and method of use of the compounds are encompassed by the instant claims.

The instant claims differ from the reference by reciting additional compounds having a halogen or methyl group in the 6, 9 or 16 positions and additional substituents

Art Unit: 1209

at the 11 position. However, it is well known that compounds having similar structures have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-1,4-pregnen-3,20-diones. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the compounds of the reference, including those of the instant claims, with reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

13. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annen et al. ('451).

Annen et al. teach a 17,21-carboxyl ester-6,16-methyl-11-hydroxy-4-pregnen-3,20-dione optionally substituted in the 9-position and having an optional double bond in the 1-position (col. 1, lines 15-42). The reference also teaches that the compounds can be used in pharmaceutical compositions for the treatment of various skin diseases (col. 2, lines 10-29).

The instant claims differ from the reference by reciting additional compounds having different groups in the 11-position. However, it is well known that compounds having similar structures have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-diones having an optional double bond in the 1-position and having similar groups

Art Unit: 1209

attached to the 9-position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the compounds of the reference, including those of the instant claims, with reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

14. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. ('971).

Page et al. teach 17,21-dicarboxylic esters of 4-pregnen-3,20-dione having either an oxo or hydroxy group in the 11-position and having substituents similar to the instant claims in the 6, 9 and 16 positions. The compounds may also contain a double bond in the 1-position (col. 1, lines 1-55). The reference also teaches the use of the compounds in pharmaceutical compositions for the treatment of corticosteroid-responsive dermatosis.

The instant claims differ from the reference by reciting additional compounds having a double bond in the 9(11)-position. However, it is well known that compounds having similar structures have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-3,20-diones having an optional double bond in the 1-position.

Art Unit: 1209

W 15. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annen et al. ('763).

Annen et al. teach 17,21-dicarboxylic esters in which the 17 and 21 positions are substituted with an acyloxy group (col. 1, lines 9-28). The references also teaches the use of the compounds for the treatment of contact dermatitis (col. 1, lines 52-59).

The instant claims differ from the reference by reciting specific species in which the 21 acyloxy is a phenoyloxy or a benzoyloxy and the 17 acyloxy is either a C₁₋₈ alkanoyloxy, a phenoyloxy or a benzoyloxy. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the compounds of the reference, including those of the instant claims, with reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

Other Matters

16. It is noted that the above rejections were made in Paper Nos. 7 and 11. The claims have not been amended and the rejections have not been argued.

Conclusion

17. This is a file wrapper continuation of applicant's earlier Application No. 08/590,624. All claims are drawn to the same invention claimed in the earlier

Art Unit: 1209

application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry Contacts

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

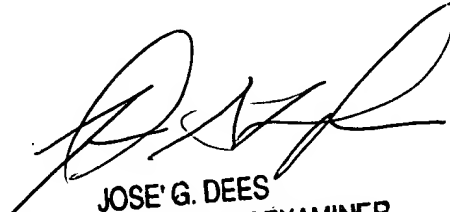
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Serial Number: 08/897,455

Page 12

Art Unit: 1209

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOSE G. DEES
SUPERVISORY PATENT EXAMINER
GROUP 1200

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November 14, 1997